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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,192	08/02/2001	David C. Turner	VTN-548	6090

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EXAMINER

WOLLSCHLAGER, JEFFREY MICHAEL

ART UNIT	PAPER NUMBER
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1791

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/921,192	Applicant(s) TURNER ET AL.	
	Examiner JEFFREY WOLLSCHLAGER	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-20, 23-32 and 34-87 is/are pending in the application.
- 4a) Of the above claim(s) 12, 13, 27-30 and 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/ are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Applicant's amendment filed November 13, 2007 has been entered. Claims 12, 13, 27-30, and 42-51 remain withdrawn from further consideration. Claims 1-3, 5-11, 14-20, 23-26, 31, 32, 34-41 and 52-87 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-8, 14-20, 23, 31, 32, 34-38, and 52-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (WO 00/04078; published January 27, 2000) in view of either of Mueller et al. (EP 0 362 137) or Vanderlaan et al. (6,087,415) and in view of Martin et al. (US 6,039,899).

The citations from Muir et al. employed in this rejection are drawn from U.S. Patent 6,893,595.

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Regarding claims 1-3, 5-7, 14-18, 31, 32, 36 and 37, Muir et al. disclose a method comprising: a) coating a molding surface of a mold with a coating of a high molecular weight coating composition, specifically a coating polymer denoted as Polymer A, (Abstract; col. 2, lines 7-12); b) dispensing a monomer mixture comprising a silicone containing hydrogel monomer into the mold (Abstract; col. 2, lines 13-17); and c) curing the monomer mixture, denoted as Polymer B, and the coating composition to produce articles such as a contact lens (Abstract; col. 2, lines 18-24).

Muir et al. further disclose that the coating polymer may be of any suitable type, specifically referring to polyvinyl alcohols (col. 4, lines 50-56). They also make reference to EP-A-0362137 as providing other suitable coating polymers (col. 4, lines 50-56). Muir et al. do not disclose a high molecular weight polymeric coating such as poly(2-hydroxyethyl methacrylate) or various of the other claimed coating polymers. Muir et al. also do not disclose the molecular weight of the polymer as being greater than 300 kD as claimed.

However, Mueller et al. disclose hydrophilic, polymeric mold coatings (Abstract; page 3, lines 14-46) such as 2-hydroxyethyl methacrylate (page 4, lines 21-35) employed to improve the wettability of a molded article (page 2, lines 39-45) having a molecular weight as high as 5,000,000 (page 5, lines 41-55) to produce an article coated with the polymeric coating. Alternatively, Vanderlaan et al. disclose coating contact lenses with polymeric materials such as poly(acrylic acid) having a molecular weight most preferably from about 100,000 to 1,000,000 by contacting the polymer and the contact lens for a period of time from about 1 minute to about 60 minutes (col. 5, lines 12-22; col. 2, lines 13-47) to provide an antimicrobial lens that can withstand washing and saline solution (col. 1, lines 59-62; col. 2, lines 20-22).

Further, Muir et al. teach the curing may be performed by various conventional methods such as with the use of a catalyst (col. 10, lines 1-10) and UV and actinic radiation (col. 11, lines

30-55). Muir et al. also teach that the cure time is optimized with initiators and chain transfer agents (col. 15, lines 11-18). Muir et al. do not explicitly teach the dwell time is less than about 5 minutes or less than about 45 seconds.

However, cure time, as taught by Muir et al., is a function of a variety of variables such as the amount and type of catalyst, sources of energy, initiators and chain transfer agents. Furthermore, the cure time is impacted by the specific composition of the coating and monomer mixture, the amount and type of diluents and other additives employed, the amount of energy applied, and the thickness of the molded article. Accordingly, the dwell time would have been readily optimized as is routinely practiced in the art to improve productivity and to reduce costs.

Furthermore, Martin et al. disclose an automated method of producing contact lenses in a fast, efficient and precise manner (col. 3, lines 37-62) within the claimed dwell times (col. 10, lines 60-67; col. 32, lines 28-41; col. 34, line 64-col. 35, line 15).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have modified the contact lens coating method disclosed by Muir et al. with the contact lens coating polymers disclosed by either of Mueller et al. or Vanderlaan et al. since Muir et al. suggest employing the polymers disclosed by Mueller et al. and Vanderlaan et al. disclose their coatings provide an antimicrobial lens that can withstand washing and saline solution (col. 1, lines 59-62; col. 2, lines 20-22).

Further, it would have been obvious to one having ordinary skill in the art at the time of the claimed invention to have employed the automated process disclosed by Martin et al. to practice the method of coating a contact lens disclosed by Muir et al. for the purpose of producing a contact lens in a fast, efficient and precise manner (Martin: col. 3, lines 37-62).

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As to claims 8, 23, and 38, Muir et al. teach the coating composition comprises, for example, an aqueous (high boiling) and organic (low boiling) solvent (col. 13, lines 48-52; col. 14, lines 30-52; col. 18, lines 54-60; col. 30, lines 45-52).

As to claims 19, 20, 34 and 35, Muir et al. provide examples of compositions of the claimed silicone hydrogel monomer mixture throughout the disclosure (col. 21, lines 16-20, for example). Vanderlaan et al. teach various silicone hydrogel monomer mixtures (col. 2, lines 38-47) and Mueller et al. also disclose conventional silicone based monomers (page 5, lines 13-15; page 6, lines 16-20; page 7, lines 37-page 8, line 6; page 8, lines 17-49; Examples).

As to claims 52-54, 64-66, and 76-78 the prior art combination teaches the method as set forth above, including the claimed materials, but does not specify the viscosity of the coating compositions. It is noted however that the same claimed materials intrinsically have the same claimed physical properties.

Further, Muir et al. teach adding a diluent, as needed, for the purpose of controlling the ability of the coating polymer to coat the surface of the mold (col. 9, lines 21-23). The diluent controls the viscosity of the material and accordingly the viscosity is controlled as required to produce a coating composition capable of coating the surface of the mold.

As to claims 55-63, 67-75, and 80-87 Muir et al. teach the coating composition comprises, for example, an aqueous (high boiling) and organic (low boiling) solvent (col. 13, lines 48-52). Muir et al. further teach various other solvents for the coating composition such as lower alkanols and glycols (col. 14, lines 30-52) and also disclose ethanol (col. 18, lines 54-60; col. 30, lines 45-52). Muir et al. exemplify ethyl acetate, an obvious variant of the closely related ester, ethyl lactate. Muir et al. further exemplify the solvents at a ratio of about 1:1 (col. 18, lines 54-60).

Claims 9, 10, 24, 25, 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (WO 00/04078; published January 27, 2000) in view of either of Mueller et al. (EP 0 362 137) or Vanderlaan et al. (6,087,415) and in view of Martin et al. (US 6,039,899), as applied to claims 1-3, 5-8, 14-20, 23, 31, 32, 34-38, and 52-87 above, and further in view of Li et al. (US 6,565,776).

As to claims 9, 24, and 39, the prior art combination teaches the method as set forth above. Further, Muir et al. teach the coating is applied by dip molding (col. 25, lines 1-18). Muir et al. do not teach that the coating of the mold is carried out by spin coating. However, Li et al. disclose that dip molding and spin coating are art recognized equivalent methods of applying a coating to a contact lens mold (col. 6, lines 42-62).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have employed an equivalent means of coating a mold, such as the spin coating method disclosed by Li et al., to coat the mold in the method disclosed by Muir et al. since it has been held that employing art recognized equivalents for the same intended purpose is *prima facie* obvious absent new or unexpected results.

As to claims 10, 25 and 40, Muir et al. exemplify using coating compositions that are applied to the surface of the mold via dip molding followed by application of 40 micro liters of monomer (col. 25, lines 1-18). The amount of coating is implicitly an order of magnitude less than the amount of the bulk material. As such, Muir et al. suggest an obvious overlapping range for the coating composition volume.

Further, Mueller et al. disclose a thickness range of 0.1 – 500 microns for the coating (Abstract). The amount employed to produce such a thickness depends on the size of the article being made and would have been readily optimized through routine experimentation.

Claims 11, 26 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (WO 00/04078; published January 27, 2000) in view of either of Mueller et al. (EP 0 362 137) or Vanderlaan et al. (6,087,415) and in view of Martin et al. (US 6,039,899), and further in view of Li et al. (US 6,565,776) as applied to claims 9, 10, 24, 25, 39 and 40 above, and still further in view of Soye et al. (US 5,316,700).

As to claims 11, 26 and 41, the prior art combination teaches the method as set forth above. Muir et al. do not teach applying pressurized air to an edge of the mold. However, Soye et al. disclose a method of removing excess material by applying pressurized air to an edge of a contact lens mold (Figure 5; col. 3, line 67-col. 4, line 2).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have employed pressurized air to the contact lens mold as suggested by Soye et al. while practicing the method disclosed by Muir et al. for the purpose as suggested by Soye et al. of removing excess lens forming material.

Claims 19, 20, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muir et al. (WO 00/04078; published January 27, 2000) in view of either of Mueller et al. (EP 0 362 137) or Vanderlaan et al. (6,087,415) and in view of Martin et al. (US 6,039,899) as applied to claims 1-3, 5-8, 14-18, 23, 31, 32, 36-38, and 52-87 above, and further in view of Turner et al. (WO 0127662). *Note: This is an alternative rejection of claims 19, 20, 34 and 35.* Citations to Turner et al. are provided from US 6,478,423.

As to claims 19, 20, 34 and 35, the prior art combination teaches the method as set forth above. Muir et al. do not employ the same claimed monomer terms when referring to the silicone hydrogel monomers. However, Turner et al. disclose a method of making a contact lens wherein an exemplified lens having desired physiological performance is provided by

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explicitly employing, in the same terms, the same materials as set forth in the claims (Abstract; col. 2, line 62-col. 3, line 32; Examples 3, 4, and 5).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to have employed the silicone hydrogel monomer disclosed by Turner et al. as the monomer employed by Muir et al. because Turner et al. disclose the composition provides for desirable physiological performance in contact lenses.

Response to Arguments

Applicant's arguments filed November 13, 2007 have been fully considered, but they are not persuasive. As an initial matter, the examiner notes that applicant's arguments directed to dwell time are addressed below. All other arguments have been substantially addressed in the rejections set forth above.

The examiner notes that applicant's definition of dwell time as set forth in the specification (i.e. the elapsed time from which the monomer mixture is dispensed into the mold until the curing commences) is the definition applied in the rejection. The examiner further notes that the initial curing steps (i.e. "precure") employed by Martin et al. are applicable to "commencing" the cure. The examiner notes that the entire reference to Martin et al. is substantially directed to reducing the cycle time of producing a contact lens' (col. 10, line 60) even including high speed robots (col. 17, lines 42; col. 20, lines 42-56) and discussing steps down to hundredths of seconds (col. 28, lines 15-65). The "precure" steps employed by Martin et al. initiate/commence the polymerization (col. 15, lines 26-38). The examiner looks for example, to col. 28 – col. 32. These columns discuss filling the mold in a matter of seconds, then clamping the mold quickly, then quickly exposing the clamped mold to actinic light to initiate polymerization. The total clamped time, including the time of exposure to actinic light is

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about 40 seconds (col. 32, lines 28-42). (It is noted that the examiner recognizes that this 40 seconds is not the dwell time to compare to the claimed dwell time).

However, the examiner submits that the clear teaching or at least the very strong suggestion/implication of Martin et al. is to fill, clamp and expose the material in order to initiate polymerization as quickly as possible (col. 28, lines 22-65; col. 31, lines 3-62; col. 32, lines 28-41). There is nothing to suggest, for example, that there is a significant delay in Martin after filling the mold but prior to clamping the mold. In fact, the examiner submits the clear teaching and suggestion is just the opposite. The examiner sees no reasonable interpretation of Martin et al. wherein the teaching or suggestion is anything other than a dwell time (i.e. the time of commencing the cure after placing the material into the mold) of less than 45 seconds and certainly less than 5 minutes.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY WOLLSCHLAGER whose telephone number is (571)272-8937. The examiner can normally be reached on Monday - Thursday 7:00 - 4:45, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. W./
Examiner, Art Unit 1791

January 30, 2008


CHRISTINA JOHNSON
SUPERVISORY PATENT EXAMINER